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<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/091,169	HEINONEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Navin Natnithithadha	3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 02 December 2005.
2. ☒ The allowed claim(s) is/are 1-8,10-32,34-51,54-58,60-65 and 67-69.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☒ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

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|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                  |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>12022005</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                         |
|   | 9. <input type="checkbox"/> Other _____.   |

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Daniel D. Fetterley on 02 December 2005.

The application has been amended as follows:

Amend claim 32-35, 38, 41, 46, 49-51, 54-56, and 58-60 as follows:

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Claim 32 (currently amended): A method for determining a change in a measured condition of the circulatory system of a subject, said method comprising the steps of:

(a) non-invasively obtaining, from the subject, an initial value for at least one selected ~~naturally occurring characteristic produced by the physiological functioning of the subject, the selected characteristic being such that a change in value of the characteristic indicates that a change in a measured circulatory system condition may also have occurred~~ variable comprising at least one of exhaled CO<sub>2</sub> amount, end tidal CO<sub>2</sub> amount, heart rate, and the amount of CO<sub>2</sub> released from the circulatory system of the subject (VCO<sub>2</sub>);

(b) carrying out a discrete measurement of the a circulatory system condition of a subject;

- (c) obtaining a further value for the at least one selected ~~naturally occurring characteristic~~ variable subsequent to carrying out the discrete measurement ;
- (d) comparing the subsequent value of the ~~characteristic~~ variable with the initial value of said ~~characteristic~~ variable to determine whether the ~~characteristic~~ obtained variable has changed in value; and
- (e) initiating a carrying out of a further discrete measurement of the ~~a~~ circulatory system condition of the subject responsive to a change in the value of the ~~naturally occurring characteristic~~ variable.

Claim 33 (canceled).

Claim 34 (currently amended): The method according to claim 32 further defined compensating the values of the selected ~~characteristic~~ variable for changes in the condition of the subject not arising from circulatory system conditions.

Claim 35 (currently amended): The method according to claim 34 further defined as compensating a selected ~~characteristic~~ variable for changes in ventilation of the subject.

Claim 38 (currently amended): The method according to claim 37 wherein the at least one selected ~~characteristic~~ variable further comprises at least one of the amount of CO<sub>2</sub> released from the circulatory system of the subject (VCO<sub>2</sub>) and the end tidal CO<sub>2</sub> amount for normal conditions of the subject.

Claim 41 (currently amended): The method according to claim 39 wherein the at least one selected ~~characteristic~~ variable further comprises at least one of the amount of CO<sub>2</sub> released from the circulatory system of the subject (VCO<sub>2</sub>) and end tidal CO<sub>2</sub> for normal conditions of the subject.

Claim 46 (currently amended): The method according to claim 32 wherein step (c) is further defined as sequentially obtaining further values of the at least one ~~characteristic~~ variable for comparison with ~~an~~ the initial value.

Claim 49 (currently amended): The method according to claim 32 further defined as allowing disturbances caused by the carrying out of the discrete measurement to subside before obtaining a further value for said at least one selected ~~characteristic~~ variable.

Claim 50 (currently amended): The method according to claim 37 further defined as allowing disturbances caused by the carrying out of the discrete measurement to subside before obtaining a further value for said at least one ~~characteristic~~ variable.

Claim 51 (currently amended): The method according to claim 32 wherein step (d) is further defined as determining whether the ~~characteristic~~ variable has changed by a predetermined amount.

Claim 54 (currently amended): The method according to claim 32 further defined as providing an indication that a change in the value of the ~~characteristic~~ variable has occurred.

Claim 55 (currently amended): The method according to claim 32 further defined as providing an indication of the amount by which the value of the ~~characteristic~~ variable has changed.

Claim 56 (currently amended): The method according to claim 32 further defined as providing an indication of the direction in which a change in the value of the ~~characteristic~~ variable has occurred.

Claim 58 (currently amended): Apparatus for determining a change in a measured condition of the circulatory system of a subject, said apparatus comprising:

(a) means for non-invasively obtaining, from the subject, an initial value for at least one selected ~~naturally occurring characteristic produced by the physiological functioning of the subject, the selected characteristic being such that a change in value of the characteristic indicates that a change in a measured circulatory system condition may also have occurred~~ selected variable comprising at least one of exhaled CO<sub>2</sub> amount, end tidal CO<sub>2</sub> amount, heart rate, and the amount of CO<sub>2</sub> released from the circulatory system of the subject (VCO<sub>2</sub>);

(b) means for carrying out a discrete measurement of a circulatory system condition of a subject;

(c) means for comparing the subsequent value of the ~~characteristic~~ variable with the initial value of said ~~characteristic~~ variable to determine whether the ~~characteristic~~ obtained variable has changed in value and for causing said means for carrying out a discrete measurement to carry out a further discrete measurement of the a circulatory system condition of the subject responsive to a change in the value of the ~~characteristic~~ variable.

Claim 59 (canceled).

Claim 60 (currently amended): The apparatus according to claim 58 further defined as including means for compensating the values of the selected ~~characteristic~~ variable for changes in the condition of the subject not arising from circulatory system conditions.

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### EXAMINER'S REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance:

Claims 1-8, 10-31, and 67-69 were allowable in the previous Office Action.

Independent claims 32 and 58: Reference to "heart rate" is made in Col 18, line 50 of the Caro, et al. This is termed a "trigger parameter" or "TP" in Fig 12 and Col 16, lines 61, et seq. The abbreviation "SP" or "state parameter" refers to the physiological parameter being monitored, in the case of Caro, et al., the blood pressure. See Col 17, line 6. In the method disclosed by Caro, et al al., as summarized in Fig. 12, the relationship between blood pressure and heart rate is determined in step 904. In step 914 of Caro, et al., to determine whether recalibration is to be carried out, it is the blood pressures SP1 and SP2, i.e., the monitored condition values, that are compared. By contrast, claim 32, step (d) of the present application calls for the selected variable, i.e., the heart rate values, to be compared, not the measured (monitored) condition of step (c) which correspond to the blood pressures of Caro, et al. Thus, the claimed method is different than that of Caro, et al. and there is no teaching or suggestion of the claimed subject matter in Caro, et al.

In addition, US 4,718,428 A, US 5,533,511 A, and US 5,876,348 A, all relate to blood pressure and not "at least one of exhaled CO<sub>2</sub> amount, end tidal CO<sub>2</sub> amount, heart rate, and the amount of CO<sub>2</sub> released from the blood of the subject."

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

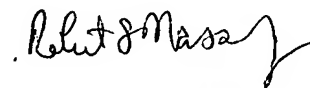
3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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05 December 2005



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